

**Notice of Allowability**

Application No.

10/075,718

Applicant(s)

CHEN, ALLAN Y.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to May 10, 2005.
2. ☒ The allowed claim(s) is/are 42-46 and 48 (renumbered as 1-5 and 6).
3. ☒ The drawings filed on 12 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |

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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Nan Wu on May 10, 2005.

1. Amend the Claims as follows:

#### IN THE CLAIMS:

Cancel claims 1-22 and 47 without prejudice.

Claim 42, line 1, after the term "radiation" insert - - - - in the treatment of breast cancer- - - - .

Claim 42, line 7, after the phrase "non-cytotoxic level" insert - - - corresponding to the effect obtained in MCF-7 cell culture using said indolocarbazole derivative at a concentration of at least 1, 2, 5 or 10 ug/ml, but not exceeding 10ug/ml.- - - - -.

#### Remarks

The above amendment places this case in condition for allowance.

The following is an examiner's statement of reasons for allowance:

The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious the claimed method for enhancing the effect of radiation in the treatment of breast cancer comprising administering to a subject in need of such treatment a radiosensitivity increasing amount of an indolocarbazole derivative having the structure A set forth in claim 42 wherein the subject is treated with radiation and the amount of indolocarbazole derivative is at a non-cytotoxic level corresponding to the effect obtained in MCF-7 cell culture using said indolocarbazole derivative at a concentration of at least 1, 2, 5 or 10 ug/ml.

The prior art of record, Chen et al. teach that the camptothecin enhanced the cytotoxicity of radiation. However, it does not teach the specified structure A set forth in claim 42 administering a radiosensitivity increasing amount at a non-cytotoxic level corresponding to the effect obtained in MCF-7 cell culture using indolocarbazole derivative at a concentration of at 1, 2, 5 and 10ug/ml.

The prior art of record, Prudhomme teaches that rebeccamycin analogues useful for having antitumor activity. However, it does not teach the radiosensitivity increasing effect of rebeccamycin by administration of non-cytotoxic level corresponding to the

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effect obtained in MCF-7 cell culture using said indolocarbazole derivative at a concentration of at least 1, 2, 5 or 10 ug/ml.

Therefore, there is not motivation to combine above reference since there is no suggestion from neither references that non-cytotoxic level of indolocarbazole combined with radiation would enhance the radiosensitivity effect.

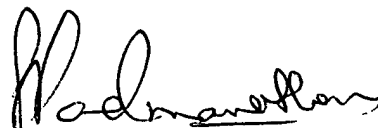
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

Jmk  
May 10, 2005